90-DAY RESPONSE

DCI Number: GDCI-035503-1628

Data Call-In Information	
Company Name	**SHARDA CROPCHEM LIMITED**
Company Address	**P.O. Box 640 HOCKESSIN, DE 19707**
DCI Type	**Generic**
Issued Date	**03/23/2017**
90-Day Response Dead ne	**07/01/2017**
CRM Informat on	**Walsh, Linsey**
Chem ca Name	**Fluometuron**
Chem ca Number	**035503**

90-Day Response Information	
Track ng Number	**CDX_DCI_2017_000450**

DCI Level Documents

File Name	File Type	MRID	CBI	Submitted Date
Cover Letter_90-Day Response Package.pdf	**Submission Cover Letter**	**N.A.**	**N**	**05/31/2017**

EPA Product Registration Number(s)	
82633-19	**I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."**

Guideline Requirement Number(s)

Guideline Requirement Number - 835.4300	
Study T t e	**Aerobic aquatic metabolism**
Protoco	**N**
Target Subm ss on Date	**03/23/2019**
Use Pattern	**A; B**
Test Substance	**TGAI**
T me Frame	**24 month(s)**
Footnote(s)	

Reg strant Response	**Developing Data**
Guideline Requirement Number - 850.2100	
Study T t e	**Avian acute oral toxicity test**
Protoco	**N**
Target Subm ss on Date	**03/23/2018**
Use Pattern	**A; B**
Test Substance	**TGAI**
T me Frame	**12 month(s)**
Footnote(s)	**9. The OCSPP 850.2100 guideline currently recommends the submission of a protocol for EPA review prior to initiation of tests conducted with passerine species. Data submitters are encouraged to consider the recommendations contained in relevant EPA reference documents (i.e., OCSPP 850.2100, EFED Guidance for Reviewing OCSPP 850.2100 Avian Oral Toxicity Studies Conducted with Passerine Birds, EFED Guidance for Use when Regurgitation is Observed in Avian Acute Toxicity Studies with Passerine Species) when preparing test protocols. A protocol does not need to be submitted to EPA for review prior to test initiation if it reflects these recommendations. If a data submitter elects to submit a protocol to EPA, in order to facilitate the review process, any aspects of a proposed study design that differ from this guidance should be noted and accompanied by a descriptive rationale which addresses why they are not expected to adversely impact the quality of the resulting study.** **10. Testing is required with a passerine species.**
Reg strant Response	**Developing Data**
Guideline Requirement Number - 850.3040	
Study T t e	**Field testing for pollinators**
Protoco	**Y**
Target Subm ss on Date	**03/23/2019**
Use Pattern	**A; B**
Test Substance	**TEP**
T me Frame	**24 month(s)**

Footnote(s)	**1. USEPA. 2012c. "Field Testing for Pollinators." Ecological Effects Test Guidelines OCSPP 850.3040. EPA 712-C-017. 2. Tier 3 study. The need for a field test for pollinators will be determined based on the results of lower-tiered tests and/or other lines of data and the need for a refined pollinator risk assessment. 11. See information and guidance identified in the EPA documents, (i) USEPA. 2012. White Paper in Support of the Proposed Risk Assessment Process for Bees. Submitted to the FIFRA Scientific Advisory Panel for Review and Comment September 11-14, 2012. Office of Chemical Safety and Pollution Prevention Office of Pesticide Programs Environmental Fate and Effects Division, Environmental Protection Agency, Washington DC; Environmental Assessment Directorate, Pest Management Regulatory Agency, Health Canada, Ottawa, CN; California Department of Pesticide Regulation; (ii) 2014 Guidance for Assessing Pesticide Risks to Bees. Office of Pesticide Programs United States Environmental Protection Agency, Health Canada Pest Management Regulatory Agency, California Department of Pesticide Regulation. June 19, 2014. https://www.epa.gov/sites/production/files/2014-06/documents/pollinator_risk_assessment_guidance_06_19_14.pdf 17. A study protocol must be submitted to, and reviewed by the EPA, prior to study initiation.**
Reg strant Response	**Developing Data**
Guideline Requirement Number - 850.4100	
Study T t e	**Seedling Emergence and Seedling Growth**
Protoco	**N**
Target Subm ss on Date	**03/23/2018**
Use Pattern	**A; B**
Test Substance	**TEP**
T me Frame	**12 month(s)**
Footnote(s)	
Reg strant Response	**Developing Data**
Guideline Requirement Number - 850.4150	
Study T t e	**Vegetative Vigor**
Protoco	**N**
Target Subm ss on Date	**03/23/2018**
Use Pattern	**A; B**
Test Substance	**TEP**
T me Frame	**12 month(s)**
Footnote(s)	
Reg strant Response	**Developing Data**

Guideline Requirement Number - 850.6100	
Study T t e	**Environmental Chemistry Methods and Associated Independent Laboratory Validation**
Protoco	**N**
Target Subm ss on Date	**03/23/2018**
Use Pattern	**A; B**
Test Substance	**TGAI**
T me Frame	**12 month(s)**
Footnote(s)	**14. Environmental Chemistry Methods and Independent Laboratory Validation are required for parent fluometuron in soil and water.**
Reg strant Response	**Developing Data**
Guideline Requirement Number - 860.1650	
Study T t e	**Submittal of analytical reference standards**
Protoco	**N**
Target Subm ss on Date	**03/23/2018**
Use Pattern	**A; B**
Test Substance	**TGAI, Degr**
T me Frame	**12 month(s)**
Footnote(s)	**15. Analytical reference standards for parent fluometuron and the metabolites trifluoromethylaniline, CGA-236431, CGA-236432, and CGA-13211 must be submitted to EPA's National Pesticide Standards Repository as they have currently expired.**
Reg strant Response	**Developing Data**
Guideline Requirement Number - SS-1155	
Study T t e	**Residues in Pollen and Nectar/Field Residue Analysis**
Protoco	**Y**
Target Subm ss on Date	**03/23/2019**
Use Pattern	**A; B**
Test Substance	**TEP**
T me Frame	**24 month(s)**

Footnote(s)	**3. Tier 2 study. The need for this study will be determined based on the results of lower-tiered studies and/or other lines of data and the need for a refined pollinator risk assessment. 16. A study protocol must be submitted to, and reviewed by the EPA, prior to study initiation. The following elements could be considered when developing study protocol(s) for the monitoring of residues in pollen/nectar. Consideration of the range of application methods and environmental conditions (e.g., soil and hydric regimes) that the target crop(s) may be under. Consideration of the attractiveness of the selected crop to pollinators. Consideration of a collection schedule sufficient to allow for an understanding of the character of residues, in the pollen/nectar and/or plant tissues, over time. Consideration of data sufficient to determine whether residues of the active ingredient and/or degradation product(s) accumulates in soil and is/are bioavailable for plant to uptake in a following planting, and therefore result in potential exposure to pollinators. Consideration of the market proportion of the selected target crop(s).**
Reg strant Response	**Developing Data**
Guideline Requirement Number - SS-1311	
Study T t e	**Honey bee adult acute oral toxicity**
Protoco	**N**
Target Subm ss on Date	**03/23/2018**
Use Pattern	**A; B**
Test Substance	**TGAI**
T me Frame	**12 month(s)**
Footnote(s)	**5. Tier 1 study. See the OECD 213: OECD Guidelines for the Testing of Chemicals. Honeybees, Acute Oral Toxicity Test. 213. http://www.oecd-ilibrary.org/environment/test-no-213-honeybees-acute-oral-toxicity-test_9789264070165-en**
Reg strant Response	**Developing Data**
Guideline Requirement Number - SS-1312	
Study T t e	**Honey bee larvae acute oral toxicity**
Protoco	**N**
Target Subm ss on Date	**03/23/2018**
Use Pattern	**A; B**
Test Substance	**TGAI**
T me Frame	**12 month(s)**
Footnote(s)	**8. Tier 1 study. OECD Test Guideline 237 may be used to develop a protocol for this study (OECD. 2013 Guidelines for Testing Chemicals. Honey bee (Apis mellifera) larval toxicity test, single exposure.) See: http://www.oecd-ilibrary.org/environment/test-no-237-honey-bee-apis-mellifera-larval-toxicity-test-single-exposure_9789264203723-en**

Reg strant Response	**Developing Data**
Guideline Requirement Number - SS-1313	
Study T t e	**Honey bee adult chronic oral toxicity**
Protoco	**Y**
Target Subm ss on Date	**03/23/2018**
Use Pattern	**A; B**
Test Substance	**TGAI**
T me Frame	**12 month(s)**
Footnote(s)	**6. Tier 1 study. OECD has not yet finalized test guidelines for chronic studies, and efforts are underway to develop standardized guidelines for assessing the effects from chronic exposure to adult and larvae in the laboratory. Discussion of the study design elements for the 10-day adult toxicity test can be found in Appendix O of the European Food Safety Authority (EFSA) guidance document: EFSA. 2013. Guidance on the risk assessment of plant protection products on bees (Apis mellifera, Bombus spp. and solitary bees). EFSA Journal 2013;11(7):3295, 266 pp. doi:10.2903/j.efsa.2013.3295. Available online at: https://www.efsa.europa.eu/en/efsajournal/pub/3295** **17. A study protocol must be submitted to, and reviewed by the EPA, prior to study initiation.**
Reg strant Response	**Developing Data**
Guideline Requirement Number - SS-1314	
Study T t e	**Honey bee larvae chronic oral toxicity**
Protoco	**Y**
Target Subm ss on Date	**03/23/2018**
Use Pattern	**A; B**
Test Substance	**TGAI**
T me Frame	**12 month(s)**
Footnote(s)	**7. Tier 1 study. OECD has not yet finalized test guidelines for chronic studies with honey bee larvae. OECD Draft Guidance Document Honey Bee (Apis mellifera) Larval Toxicity Test, Repeated Exposure. https://www.oecd.org/env/ehs/testing/Honeybee%20larval%20rep%20expo_REV%20following%20April%202015%20expert%20meeting_Draft%2020%20July%202015.pdf** **17. A study protocol must be submitted to, and reviewed by the EPA, prior to study initiation.**
Reg strant Response	**Developing Data**
Guideline Requirement Number - SS-1319	
Study T t e	**Semi-field testing for pollinators (tunnel or colony feeding studies)**

Protoco	**Y**
Target Subm ss on Date	**03/23/2019**
Use Pattern	**A; B**
Test Substance	**TGAI or TEP**
T me Frame	**24 month(s)**
Footnote(s)	**4. Tier 2 study. The need for a semi-field test for pollinators (i.e., either a field-feeding test or a tunnel test) will be determined based on the results of lower-tiered tests and/or other lines of evidence, and the need for a refined pollinator risk assessment. 12. Formal guidelines for semi-field tests do not yet exist; however, information that can help guide the development of a semi-field tunnel test protocol can be found at OECD 75, see: OECD. 2007. Series on Testing and Assessment Number 75. Guidance document on the honey bee (Apis mellifera L.) brood test under semi-field conditions. Environmental Directorate Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology. ENV/JM/MONO(2007)22. 31-Aug-2007. http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2007)22&doclanguage=en 13. For field-feeding studies see: Oomen et al. 1992: Oomen, P. A. A. DeRuijter and J. Van der Steen. 1992. Method for honey bee brood feeding tests with insect growth-regulating insecticides. Bul OEPP/EPPO Bulletin 22: 613-616. 17. A study protocol must be submitted to, and reviewed by the EPA, prior to study initiation.**
Reg strant Response	**Developing Data**
Submitter Information	
Subm tter	**James Wagner**
Subm tted Date	**05/31/2017**
Add t ona Contact(s)	**cheryl@wagnerreg.com**